CLAIMS

We claim:

1. A method of analyzing a tissue sample, comprising:

contacting a Direct Cell Target Analysis (DCTA) molecule with the tissue sample under conditions that allow at least a portion of the DCTA molecule to interact with at least a portion of the tissue sample, wherein the DCTA molecule comprises a targeting moiety, capable of localizing the DCTA to target cells or components within the sample; and an active moiety, capable of generating a detectable signal or product;

activating the active moiety of the DCTA molecule; and

detecting the signal or product generated by the activated second moiety, thereby analyzing the tissue sample.

2. The method of claim 1, wherein the tissue sample comprises biopsy material, a tissue section, a cell culture preparation, a cytology preparation, cells *in vitro*, or cells *in vivo*.

3. The method of claim 1, wherein the targeting moiety comprises a variable region of an antibody binding domain.

4. The method of claim 1, wherein the targeting moiety is a generalized targeting moiety and comprises a variable region of a secondary antibody binding domain.

5. The method of claim 1, wherein the targeting moiety comprises a ligand that specifically binds to a receptor protein within or upon target cells in the tissue sample.

6. The method of claim 1, wherein the targeting moiety comprises a nucleic acid molecule capable of hybridizing to a complementary sequence within the target tissue.

7. The method of claim 1, wherein the active moiety comprises a reverse transcriptase molecule and the detectable products are cDNA transcripts.

8. The method of claim 1, wherein the active moiety comprises a DNA polymerase molecule and the detectable products are DNA transcripts.

9. The method of claim 7 or 8, wherein one or more components that are necessary for generation of the detectable products are externally provided.

10. The method of claim 9, wherein at least one of the provided components is a labeled nucleotide.

11. The method of claim 10, wherein the labeled nucleotide is labeled with an isotope or a fluorophore.

12. The method of claim 1, wherein the active moiety comprises a lactoperoxidase molecule and the detectable products comprise iodinated tryptophan or tyrosine residues.

13. The method of claim 1, wherein the active moiety comprises lactoperoxidase and the detectable products comprise ^{125}I labeled proteins.

14. The method of claim 1, wherein the detectable signal is visualized without physical separation of the analyzed products from the sample.

15. The method of claim 1, wherein the detectable products are separated from the sample prior to analysis.

16. The method of claim 1, further comprising quantifying the detectable products.

17. The method of claim 1, wherein the detectable products are amplified during analysis.

18. The method of claim 1, wherein the DCTA molecule comprises at least one targeting moiety and at least one active moiety each covalently linked to a polymer linker.

19. The method of claim 1, wherein the DCTA molecule comprises a poly(l-lysine hydrobromide) polymer conjugated to lactoperoxidase and goat anti-mouse IgG antibody.

20. A method for screening for a disease in a subject, comprising using the method of claim 1 to analyze a tissue sample from the subject for the presence of a protein, or a nucleic acid encoding the protein, wherein the presence of the protein or the nucleic acid encoding the protein in sample from the subject is indicative of the disease in the subject.

21. A method for screening for a disease in a subject, comprising using the method of claim 1 to compare expression levels of a nucleic acid in a tissue sample from the subject, wherein elevated or decreased expression levels of the nucleic acid compared to a sample from a control subject known not to have the disease is indicative of the disease in the subject.

22. A method for screening for a disease in a subject, comprising using the method of claim 1 to screen for a nucleic acid in a sample from the subject, wherein absence of the nucleic acid in the target cells is a biochemical marker of disease in the subject.

23. A method for screening for a disease in a subject, comprising using the method of claim 1 to screen for a hormone in a sample from the subject, wherein the absence of the hormone in the target cells is a biochemical marker of disease in the subject.

24. The method of claim 1, wherein the method is a method for screening for a disease in a subject, comprising using the method of claim 1 to screen for the presence of a mutation in the nucleic acid in a sample from the subject, wherein the presence of such a mutation is a genetic marker of disease in the subject.

25. The method of any one of claims 22 through 24, wherein the disease comprises a neoplasia.

26. The method of any one of claims 1 through 24, wherein the DCTA is automated.

27. A kit for analysis of a sample, comprising a DCTA molecule.

28. The kit of claim 27, wherein the moieties comprising the DCTA molecule are provided separately.

29. The kit of claim 27, wherein the DCTA molecule is a standardized DCTA molecule.

30. The kit of claim 27, wherein the DCTA molecule comprises a targeting moiety specific for a disease-linked molecule.

31. The kit of claim 30, wherein the disease-linked molecule is a disease-specific protein or a disease-specific nucleic acid molecule.

32. A kit for detection of a mutation in a sample, comprising a DCTA molecule capable of targeting cells of interest in the sample and producing a detectable signal, whereby the signal provides information regarding whether the mutation is present.

33. A kit for determining whether a subject has a disease, comprising a DCTA molecule capable of targeting cells of interest in the sample and producing a detectable signal, whereby the signal provides information regarding whether the subject has the disease.